Remarks

Applicant wishes to thank the Examiner for the telephonic interview conducted on May 7, 2003 regarding the subject application. In light of the interview, the claims have been amended to advance prosecution of the subject application. The claims now recite, *inter alia*, a method for feeding an animal comprising feeding the animal a corn grain obtained from a transgenic corn plant comprising in its genome a chimeric gene selected from the group recited in the claims. Sequence identity has also been modified as discussed below. Support for this can be found in the specification on pages 1-10 and in the Examples. Thus, no new matter has been added.

It is respectfully submitted that such claims are entitled to priority of provisional application 60/088987.

A copy of U.S. Patent No. 6,433,252 B1 is submitted herewith along with PTO form 1449 and the appropriate statement and fee. The '252 patent corresponds to WO 99/60129 published November 25, 1999 which has been previously cited.

Corrected drawings are submitted herewith. The drawings have been corrected to address the objections noted on the PTO 948 mailed with paper number 12.

The claims have also been amended to delete any reference to a non-elected invention.

Sequence identity has been changed to 90%. Support for this can be found in the specification on page 14 at lines 9-26 and in Example 1 which concerns corn fad2-2 cDNA and genomic DNA clones.

The term "or a functionally equivalent subfragment of the isolated has been replaced by referencing a subsequence of the appropriate SEQ ID NO having at least 500 nucleotides wherein the subsequence is used to cosuppress an endogenous gene encoding either a corn delta-9 stearoyl ACP desaturase or a corn delta-12 desaturase. Support for this can be found in the specification on page15 at lines 7-8 and on page 17 at lines 10-14 which references U.S. Patent No. 5,231,020 which issued to Jorgenson et al. on July 27,1993 and in Example 1 of the instant specification which states in part that:

A corn embryo cDNA library was screened using a radioisotopically-labeled DNA fragment obtained by PCR and containing the corn gene for delta-12 desaturase ("fad2-1", WO 94/11516, and set forth in SEQ ID NO:1). A second delta-12 desaturase cDNA clone was identified on the basis of its sequence. The second gene for delta-12 desaturase is designated fad2-2.

The full-length cDNA sequence is shown in SEQ ID NO:2. It encodes a polypeptide of 392 amino acids (translation frame: nucleotide 176-1351). The coding region of the corn fad2-2 shares significant sequence identity with fad2-1: they share

88% identify at the amino acid level, and 92% at the nucleotide level. They also possess 77% identity at the 5'-untranslated region, and 64% at the 3' end.

A full-length or a portion of the coding region of either one of genes in either antisense or sense approach may be used to suppress both the fad2-1 and fad2-2 genes or gene products, due to the significant homology in the coding region between the fad2-1 and fad2-2 genes, and thus produce a high oleate phenotype in transgenic corn. (Emphasis added.)

Withdrawal of the rejection of claims 172-176 under 35 USC §112, second paragraph, is respectfully requested in view of the above discussion and amendments.

Claims 172 – 176 were rejected under 35 USC §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims have been amended to clarify that the method is for feeding an animal comprising feeding the animal a corn grain obtained from a transgenic corn plant comprising in its genome a chimeric gene selected from the group recited in the claims.

It is clear from the discussion on pages 1-10 of the specification and in the Examples that there is great interest in animal feed. It is respectfully submitted that the issues raised with respect to the term " carcass quality improving amount" are rendered moot by virtue of the amendments to the claims.

It is stated on page 7 of the Office Action that the "specification does not teach any general mechanism by which the introduced nucleic acids are effecting the fatty acid content of the plants. The specification does not teach plants with a broad range in changes in fatty acid composition, only plants with high stearic acid content or high oleic acid content. The specification also does not teach plants which comprise both of the desaturases in which altered lipid content is observed. . . . The specification teaches plants in which sense and anti-sense nucleic acids encoding corn delta-9 stearoyl ACP desaturase are introduced into plants, and in both instances the resulting plant displayed high saturate fatty acid composition. The mechanism by which this occurs is unclear, and therefore, it is not possible to predict the effect that adding other nucleic acids to the plants would have on the plant. . . . The effects of inclusion of both transgenes in a plant are unknown, and thus it is impossible to know such a plant would effect animal carcass quality."

In addition, sequence identity has been changed to 90%.

Any concerns regarding effects on animal carcass quality have been obviated in view of the current claim amendments. It is respectfully submitted that no undue experimentation would be needed to practice the claimed invention.

The law is well settled that an inventor need not have understood how the invention achieves its useful result. It was stated in Radiator Specialty Co. v. Buhot, 4 USPQ at 205, 209 (3rd Cir. 1930) that "It is with the inventive concept, the thing achieved, not with the manner of its achievement or the quality of the mind which gave it birth that the patent law concerns itself." More recently, it was observed by the court in Life Technologies, Inc. v. Clontech, 56 USPQ2d 1186, 1190 (Fed. Cir. 2000) that the path that leads an inventor to the invention is expressly made irrelevant to patentability by statute. It is well known that patentability is not negatived by the manner in which the invention was made.

What is important is whether one skilled in the art can make and use the invention without engaging in undue experimentation. The Court of Appeals for the Federal Circuit stated in Plant Genetic Sys., N.V v. DeKalb Genetics Corp. 65 USPQ2d 1452 (Fed. Cir. 2003) that to be enabling the patent specification must teach those skilled in the art how to make and use the full scope of the claimed invention without "undue experimentation." The law does not require that "mechanisms" by which an invention operates necessarily be explained.

It is respectfully submitted that Applicants clearly set forth to those of ordinary skill in the art how to make and use the claimed the claimed invention, specifically, how to make constructs and transform corn plants so as to alter the lipid profile of a transformed plant which comprises the construct in its genome.

Example 7 describes how the constructs were made, including a construct identified as pBN414 which contained a fused trait gene of fad2-1 and delta-9 desaturase, both in the sense orientation (as shown in Figure 3E). Part A of Example 8 describes corn transformation methodology.

What the law requires is that those skilled in the art be able to make and use the full scope of the claimed invention without undue experimentation. Given the detailed information provided in the specification, one skilled in the art would be able to practice the claimed invention without undue experimentation.

The Office Action alleges on page 10 that "the specification provides no guidance as to how instant SEQ ID NO:38-49 can be modified yet still retain their ability to promote transcription of a heterologous sequence when paired with the shrunken 1 intron/exon."

The claims have been amended to recite an isolate nucleic acid fragment comprising a corn oleosin promoter consisting essentially of the nucleotide sequence set forth in any of SEQ ID NOS:38=40 and 42-49. Furthermore, attention is kindly invited to Example 6 (pages 36 – 41) which discusses an oleosin 16 kDa promoter deletion assay. This example discusses in great detail how the relative activities of promoters from oleosin 16 kDa, and globulin-1, were analyzed using a transient expression assay.

Thus, one of ordinary skill in the art should have no difficulty making and using the claimed invention.

Claims 172-176 were rejected under 35 USC §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims recite a method for feeding an animal comprising feeding the animal a corn grain obtained from a transgenic corn plant comprising in its genome a chimeric gene selected from the group recited in the claims.

As is discussed above the term "subfragment that is functionally equivalent" has been replaced has been replaced by referencing a subsequence of the appropriate SEQ ID NO having at least 500 nucleotides wherein the subsequence is used to cosuppress a nucleic acid fragment encoding either a corn delta-9 stearoyl ACP desaturase or a corn delta-12 desaturase.

Example 7 describes the preparation of corn embryo/aleurone specific constructs with lipid trait genes. It is stated on page 41 at lines 18-27 that

> Expression constructs comprising a maize oleosin 16 kDa promoter (0.9 kb in length, Table 1 and 2, and SEQ ID NO:39), an intron1/exon1 element (1.1 kb) from the shrunken-1 gene located between (3' to) the promoter and (5' to) the cDNA fragment, a cDNA fragment encoding a portion of the trait gene in either sense or antisense orientation with respect to the promoter, and a Nos 3'-end located 3' to the cDNA fragment, were constructed and used in corn transformation to alter the level of the enzyme encoded by the trait gene in corn grains (Figure 3B-3F). **The construct design is suitable to express any target trait gene not mentioned in this patent in a corn embryo/aleurone-specific manner. The selectable marker on the vector backbone may be any antibiotic (e.g., ampicillin, hygromycin, kanamycin) resistant gene. (Emphasis added.)**

It is alleged on page 11 of the Office Action that "with regard to the functionally equivalent subfragment language, the mechanism by which the introduced nucleic acids act in plants is unknown, and therefore the 'function' of the nucleic acids is unknown."

As was discussed above, patentability is not negatived by the manner in which the invention is made. Applicant has shown how to modify the fatty acid profile of corn grain to product grain having a high saturate fatty acid profile or a high oleic acid profile. Information is also provided on page 50 of the specification how to produce transgenic corn with high levels of saturated and oleic acid in kernels.

Applicants have provided detailed information how to modify the lipid profile of corn. Thus, it is respectfully submitted that Applicant was indeed in possession of the claimed invention at the time the application was filed.

It is believed that comments provided on pages 12 –19 of the Office Action are addressed by the foregoing comments and amendments.

It is respectfully submitted that the claims are now in form for allowance which allowance is respectfully requested.

The Examiner is encourage to contact the undersigned if there are any questions or if further clarification is needed.

A petition for a two (2) month extension of time and an information disclosure statement accompany this response.

Please charge any fees or credit any overpayment of fees which are required in connection with the filing of this Response and Petition for Extension of Time to Deposit Account No. 04-1928 (E. I. du Pont de Nemours and Company).

Respectfully submitted,

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